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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/862,690	05/22/2001	Robert John Cottone, JR.	1133279-0004	8698

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PATENT DEPARTMENT
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER

WEBB, SARAH K

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/862,690

Applicant(s)

COTTONE, ET AL.

Examiner

Sarah K. Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-10 and 12-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-10 and 12-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 states that the connection elements connect peaks and valleys, but Claim 27 contradicts this limitation by requiring the connection elements to connect two peaks.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-6,14-19,24-27,32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,042,597 to Kveen et al. in view of US Patent No. 5,913,897 to Corso, Jr. et al.

Kveen discloses a double-helix stent pattern that includes a first helix (11) comprising non-sinusoidal undulations. The undulations are considered to meet the limitation "nonsinusoidal" because the curves of the undulations in the first helix (11) are too sharp to be considered sinusoidal curves. The second helix is formed of connection elements (14) that connect peaks to valleys of adjacent turns of the first helix. The direction of the second helices is clearly defined by lines (16) in Figure 1, which is opposite to the direction of the first helix. Kveen includes nitinol as a stent material (column 1, lines 45). In Figure 4, the first helix terminates in a transition zone that forms flat ends of the stent.

Kveen meets of the limitations of claim 1, except that all of the undulations are connected by connection elements (14). Corso discloses another double-helix stent that includes a first helix (24) comprising an undulation pattern and a second helix defined by connection elements (28) (column 5, lines 16-30). Figures 2 and 8 clearly define the opposite directions (angles A and B) in which the helices proceed. Corso connects fewer than all of the undulations and teaches that only 2 to 4 second helices are necessary to provide a uniformly expanding and flexible stent (column 6, lines 30-51). It would have been obvious to one of ordinary skill in the art at the time the invention was made to connect fewer than all of the undulations of the first helix of Kveen, as Corso teaches that a flexible, uniformly expanding stent may be obtained by only connecting two to four undulations per turn. This modification would reduce the material needed to form the stent and lower the cost of manufacturing.

3. Claims 8-10,12,20-22, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kveen et al. in view of Corso, Jr. et al., as applied above, and further in view of US Patent No. 5,925,061 to Ogi et al.

Kveen, as modified above by Corso, does include transition zones at the ends of the stent, as shown in the embodiment of Figure 4, but the amplitude of the undulations decreases as the first helix proceeds around the turn. Kveen and Corso also fail to include closed circumferential elements at both ends of the stent. Ogi et al. discloses another double helix stent in Figure 8 with a first undulating helix (35m) and a second helix defined by connection elements (18). Ogi teaches that another way to form a transition zone at an end of the stent to create flat ends is to increase the amplitude of the undulations of the first helix as it proceeds around the turn and include closed circumferential elements at both ends of the stent (column 9, lines 10-

22). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the transition zones of the modified Kveen stent by increasing the amplitude of the undulations and connecting closed circumferential elements to each end of the helical pattern, as taught by Ogi. This is simply a substitution of functionally equivalent structures since both types of transition zones provide a stent with flat ends.

4. Claims 13, 23, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kveen in view of Corso, Jr. et al. and Ogi et al., as applied above, and further in view of US Patent No. 6,315,794 to Richter.

Kveen, Corso, and Ogi fail to form the closed end elements from radiopaque material. Richter discloses a stent in Figure 3A that has zigzag rings connected by links. Richter teaches that the closed circumferential elements (111,112) on either end of a stent should be radiopaque, because this type of marking is useful for accurate positioning of the ends of the stent in critical circumstances (column 4, lines 50-65). Richter goes on to state that the elements (11,112) are formed of suitable radiopaque materials, such as gold and silver. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the closed circumferential elements of the modified Kveen stent from a radiopaque material, as taught by Richter, in order to provide greater accuracy in positioning of the stent.

Response to Arguments

5. Applicant's arguments filed 12/21/05 have been fully considered but they are not persuasive. Applicant argues that the shape of the undulations in Figure 8 of Ogi et al. does not meet the limitations "nonsinusoidal" and "zigzag." The office considers the undulations in Figures 4 and 8 of Ogi et al. to meet this limitation, because the

curves are sharper than that of sinusoidal wave. A "sinusoidal" pattern is shown in Figure 3 (as pointed by applicant), but Ogi explains that this sinusoidal pattern is clearly distinguishable from the "nonsinusoidal" pattern of Figure 4 by sharper turns (column 7, lines 15-25). Further, the undulating pattern disclosed in Figure 4 of Ogi is very similar to the "nonsinusoidal" pattern of applicant's disclosure.

6. Applicant also argues that the connection elements of Ogi do not form a "second helix." The prior art is not required to describe a "second helix" structure. The prior art is only required to disclose a stent pattern that includes connection elements that form a "second helix." Examiner's arrows in the prior office action were simply meant to clearly show applicant the direction in which the second helix of the Ogi stent proceeds. The new rejections include art with first and second helices defined by lines and angles, which clearly points out the direction in which the second helices proceed.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. USPAP No. US 2003/0167084 discloses a stent pattern with similar features to the claimed invention.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K. Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW

3/30/06



JULIAN W. WOO
PRIMARY EXAMINER